NONIN

APR 19 2012

K 112843

510(k) Summary

Submitter:	Nonin Medical, Inc.
Contact Person:	Brodie Pedersen Senior Regulatory Engineer Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Phone:	763-553-9968
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Date Prepared:	September 28, 2011
Trade Name:	**Onyx® Vantage 9590**
Classification Name and Number:	Class II, 21 CFR 870.2700
Product Code:	DQA
Predicate Device(s):	Nonin's Onyx Vantage 9590 finger pulse oximeter is substantially equivalent to the Nonin Model 9550 Onyx II finger pulse oximeter cleared by the FDA in K053130 on 1/11/2006.
Indications for Use:	**Onyx Vantage 9590** The Nonin® Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits, including the thumb and toes, that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.

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Device Description:

Onyx Vantage 9590 is a small, lightweight, portable, digit pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. Light emitting diodes (LEDs) are contained within the device along with the photo detector, which is on the opposite side of the probe from the LEDs. The SpO2 and pulse rate are displayed on the LED display contained within the device. A tricolor LED provides a visual indication of the pulse quality signal, while blinking at the corresponding pulse rate. This display changes colors to indicate the pulse quality that may affect the readings: green indicates a good pulse quality signal, yellow indicates a marginal pulse quality, and red indicates an inadequate pulse signal. All associated electronics and the microprocessor are within the sensor, which is activated by placing on a patient's digit. This simple operation activates the internal circuitry automatically upon application. The device is intended for spot-checking of adult and pediatric patients who are well or poorly perfused on digits, including the thumb and toes.

Functional and Safety Testing:

Nonin's Onyx Vantage 9590 Finger Pulse Oximeter has successfully undergone both laboratory and clinical hypoxia accuracy testing in order to ensure that it has appropriate performance, functional features to fully comply with ISO 9919:2005 and is substantially equivalent to the predicate device.

Conclusion:

Nonin's Onyx Vantage 9590 is substantially equivalent to the Model 9550 Onyx II Finger Pulse Oximeter manufactured by Nonin Medical, Inc. and cleared by the FDA under K053130 on 1/11/2006.

The results of testing lead to the conclusion that the revised indications for use and labeling are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. Brodie Pedersen
Senior Regulatory Engineer
Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441

APR 19 2012

Re: K112843
Trade/Device Name: Onyx® Vantage 9590
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 13, 2012
Received: April 16, 2012

Dear Mr. Pedersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(K) Number: _____

Device Name:

Nonin Medical, Inc. Onyx Vantage 9590

Indications for Use:

Onyx Vantage 9590

The Nonin® Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits, including the thumb and toes, that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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